1. **TITLE:** IS4000 Basic Instruments Worst Case Instrument Identification and Rationale
2. **ORIGINATOR:** Andrew Crews
3. **PURPOSE:** The purpose of this document is to identify instruments with the highest probability of mechanical failure during their intended life in the initial IS4000 basic instrument suite (listed in table 1 below), and to provide a rationale for each selection. Instruments with the highest probability of mechanical failure during its intended life will be referred to as “worst case” instruments. Instruments are grouped based similarities in design and function in table 2. From these groups, the worst case instrument, based on design and intended use, is selected to represent the other instruments within that group.
4. **SCOPE**. The identification of worst case instruments applies to the IS4000 basic instruments suite. A full list of the initial IS4000 basic instruments is provided below in table 1.

Name	Part No.
Potts Scissors	470001
Small Clip Applier	470003
Large Needle Driver	470006
Black Diamond Micro Forceps	470033
Long Tip Forceps	470048
ProGrasp Forceps	470093
Snap-Fit Instrument	470157
Micro Bipolar Forceps	470171
Maryland Bipolar Forceps	470172
Monopolar Curved Scissors	470179
Resano Forceps	470181
Permanent Cautery Hook	470183
Permanent Cautery Spatula	470184
Fenestrated Bipolar Forceps	470205
Tenaculum Forceps	470207
Cardiac Probe Grasper	470215
Large Clip Applier	470230
Atrial Retractor Short Right	470246
Dual Blade Retractor	470249
Mega SutureCut Needle Driver	470309
Small Grasping Retractor	470318
Medium-Large Clip Applier	470327
Curved Bipolar Dissector	470344
Tip-up Fenestrated Grasper	470347

Table 1 – IS4000 Initial Basic Instrument Suite

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
TRIAL EXHIBIT 541
Case No. 3:21-cv-03496-AMO
Date Entered ______
By ______
Deputy Clerk

5. REFERENCE(S):

861445-02T	Top Level Test Plan for IS4000 Instruments
853029	DOP, Signature Matrix

6. DEFINITIONS AND INSTRUMENT LAYOUT:

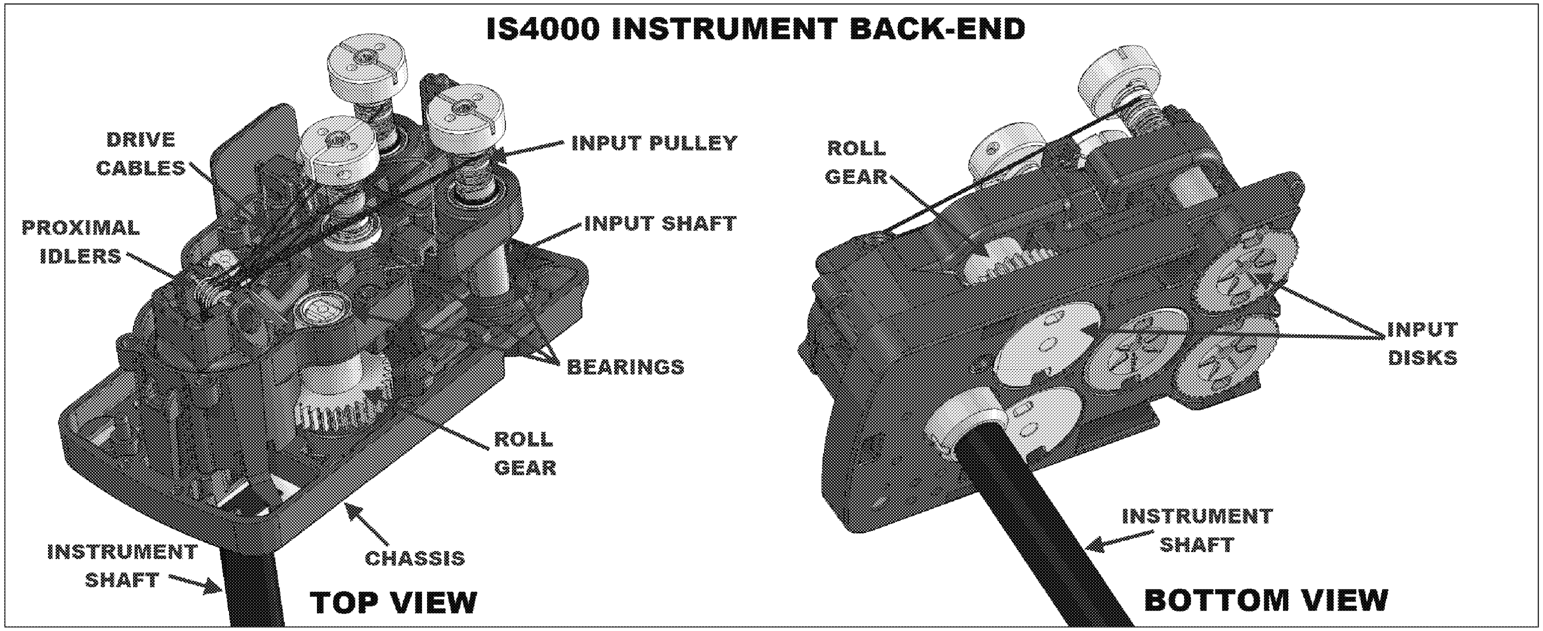

Figure 1 - IS4000 Instrument Back-End (Cover not shown)

6.1. **Bearings –** Locate and provide free rotation of input shafts.
6.2. **Carriage –** The portion of the IS4000 system arm to which the instrument mates. Contains drive motors which supply torque to instrument input disks.
6.3. **Chassis –** Frame/support structure for back-end components. Mates with and secures instrument to system carriage.
6.4. **Drive Cables –** Transmit force between input and distal pulleys (e.g. yaw/pitch).
6.5. **Input Pulley/Shaft –** Transmit torque from input disks to drive cables
6.6. **Instrument Shaft –** Connects distal assembly to back-end, mounting point for proximal clevis, houses drive cables, transmits roll torque.
6.7. **Proximal Idlers –** Supports and routes drive cables where they enter shaft.

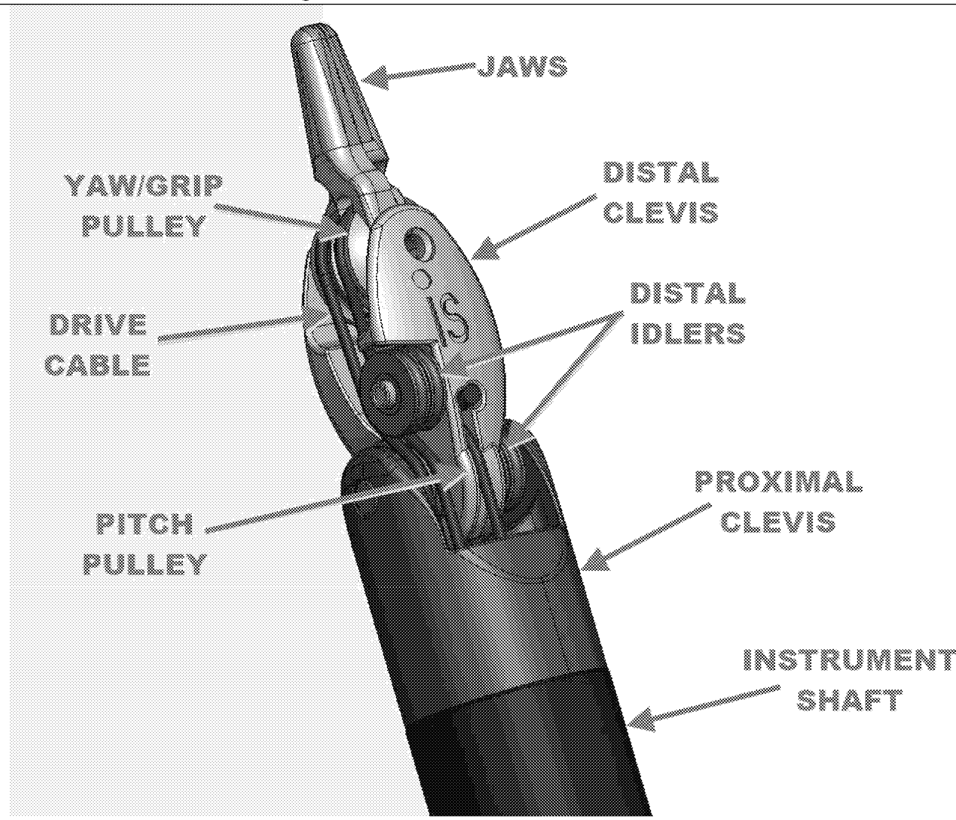

Figure 2 - IS4000 Instrument Distal Assembly (Large Needle Driver Shown)

6.8. **Distal Clevis –** Provides pitch actuation, mounting point for instrument jaws and distal idlers
6.9. **Distal Idlers –** Route drive cables through distal assembly.
6.10. **Jaws –** Manipulate/Grip Tissue or Surgical accessories (e.g. clips or needles)
6.11. **Pitch Pulley –** Translates drive cable force into pitch torque actuates distal clevis.
6.12. **Proximal Clevis –** Secures distal assembly to instrument shaft provides mounting point for distal clevis.
6.13. **Yaw/Grip Pulley –** Translates drive cable force into yaw/grip torque actuates jaws.

7. RATIONALE AND INSTRUMENT COMPARISON

The probability of a mechanical failure is a product of inherent design loads and intended clinical use cycle. Design load and clinical use cycle are further defined below.

Design load is a comparative ranking of the stress an instruments drivetrain components are subject to during use. Drivetrain components which are unique to the IS4000 instruments (and thus must be verified) include the drive cables, instrument shaft, chassis, pulleys, and bearings. All of the instruments covered by this document share identical back-end drive-train components, and vary only in their distal assemblies. The maximum stresses result from the following factors:

- The maximum torque input from the system carriage (which is defined for each instrument type). Torque at the input pulleys is directly proportional to the tension in the attached cables. Higher cable tension contributes to cable fatigue and more rapid cable failure.
- Torque multipliers inherent to the instrument. Torque multipliers result from pulley diameter ratios within the instrument drivetrain (e.g. a distal jaw pulley of smaller diameter than the input pulley resulting in higher torque at the grip then at the input).
- The diameter of the instrument pulleys. The localized (bending) stresses are higher where the cables wrap around the pulleys. The tighter the bend the higher localized stress which contributes to cable fatigue and more rapid cable failure.

Although jaw sizes vary across the IS4000 instruments, the maximum loading is still dictated by the maximum torque limit set for that instrument. Thus, regardless of the geometry or length of a distal component and its corresponding potential for force-amplification due to lever-arm, the actual force that the distal components will experience is limited by the torque limit (at that components pivot point). Any forces which exceed the torque limit result in instrument back-driving (i.e. the distal components will move in a direction which relieves the force).

Clinical use cycle is a comparative ranking of the quantity of manipulator motion a given instrument is expected to experience in the course of its intended use, as determined by Clinical Engineering, based on expected clinical use. The quantity of manipulator motion is a primary factor in the wear and cyclic fatigue of critical instrument components.

Table 2 (below) groups the IS4000 basic instrument suite into groups based similarities in design and function. From each of these groups, one or more instruments have been identified as worst case based upon a consideration of their design load and clinical use cycle. These selections are indicated by a check-mark in the "Worst Case" column. Testing of the selected instruments is therefore representative of the rest of the group from which it was selected.

	Instrument Name	Worst Case
One-Finger (Jawless) Instruments	Snap-Fit Instrument	
	Permanent Cautery Hook	☑
	Permanent Cautery Spatula	
Bipolar Instruments	Micro Bipolar Forceps	
	Maryland Bipolar Forceps	☑
	Fenestrated Bipolar Forceps	
	Curved Bipolar Dissector	
Needle Drivers	Large Needle Driver	☑
	Black Diamond Micro Forceps	☑
	Mega SutureCut Needle Driver	☑
Graspers/Retractors	Long Tip Forceps	
	ProGrasp Forceps	☑
	Resano Forceps	
	Tenaculum Forceps	☑
	Cardiac Probe Grasper	
	Atrial Retractor Short Right	
	Dual Blade Retractor	
	Small Grasping Retractor	
	Tip-Up Fenestrated Grasper	
Scissors	Monopolar Curved Scissors	☑
	Potts Scissors	
Clip Appliers	Small Clip Applier	☑
	Medium-Large Clip Applier	
	Large Clip Applier	

Individual rationales for the worst-case instrument/instrument(s) for each group listed in table 2 are given below:

One-Finger (Jawless) Instruments: **Permanent Cautery Hook** (*aka "Hook"*) – The Hook and Permanent Spatula (*aka "Spat"*) instruments are identical except in the shape of their distal end effector (curved hook vs. flat spatula), with the Hook being slightly longer over-all. Both the Hook and Spat utilize a distal assembly which is primarily composed of Ultem plastic (yaw pulley, distal and proximal clevis) and both have the same torque limits. The Hook has a more rigorous life cycle than the Spat, in terms of the amount of distal motion during a surgical procedure and the amount of force it exerts on patient anatomy during use, which is directly related to the level of material stress within the instrument. The Snap-Fit instrument life cycle is less rigorous than either the hook or the spat, with a relatively low amount of distal motion during a surgical procedure, and less force exerted during use. The snap-fit instrument also uses a stainless steel distal assembly which has greater strength than the plastic assemblies on the Hook/Spat and has a lower torque limit.

Bipolar Instruments: **Maryland Bipolar Forceps** (*aka "Maryland"*) – All of the instruments within the Bipolar group utilize the same distal components with the exception of jaws. All of the bipolar instruments have the same torque limits, except the Micro Bipolar Forceps, which has a lower limit. The Maryland has the most rigorous life cycle in this group in terms of the amount of distal motion, and forces exerted.

Graspers: **Prograsp Forceps, Tenaculum Forceps** – The Prograsp Forceps exert an amount of force that is mid-level for their group but have been selected for testing due to their relatively rigorous clinical life cycle, which involves a relatively large amount of distal motion. The Tenaculum Forceps has the highest level of cable tension in this category and is thus selected for testing.

Scissors: **Monopolar Curved Scissors** – The Monopolar Curved Scissors (*aka "MCS"*) instrument has the highest design load in its category and a more rigorous life cycle than the Potts Scissors in terms of the amount of distal motion. Further, he MCS is a Monopolar cautery enabled instrument whereas the Potts scissors is a non-energy or "cold" instrument. The application of cautery energy has the potential to cause a more rapid degeneration of the scissor blade edges than cold cutting alone.

Clip Appliers: **Small Clip Applier** – All of the instruments in the Clip Applier category have the same clinical life cycle. The Small Clip Applier has significantly higher design loads than the Medium-Large Clip Applier.

8. Attachments:

i. Engineering Comparison table (attachment 2 to 861445-02T)